

Calendar No. 173

109TH CONGRESS
1ST SESSION**S. 1420****[Report No. 109–107]**

To amend the Federal Food, Drug, and Cosmetic Act with respect to medical device user fees.

IN THE SENATE OF THE UNITED STATES

JULY 18, 2005

Mr. ENZI (for himself, Mr. KENNEDY, Mr. BURR, Mr. DEWINE, Ms. MIKULSKI, Mr. DODD, Mrs. MURRAY, and Mr. HATCH) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

JULY 25, 2005

Reported by Mr. ENZI, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to medical device user fees.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medical Device User
5 Fee Stabilization Act of 2005”.

1 **SEC. 2. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND**
 2 **COSMETIC ACT.**

3 (a) **DEVICE USER FEES.**—Section 738 of the Federal
 4 Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amend-
 5 ed—

6 (1) in subsection (b)—

7 (A) after “2004;”, by inserting “and”; and

8 (B) by striking “2005;” and all that fol-
 9 lows through “2007” and inserting “2005”;

10 (2) in subsection (c)—

11 (A) by striking paragraphs (1), (2), and
 12 (3);

13 (B) by redesignating paragraphs (4), (5),
 14 and (6) as paragraphs (1), (2), and (3), respec-
 15 tively;

16 (C) in paragraph (1), as so redesignated,
 17 by—

18 (i) striking the paragraph heading
 19 and inserting “2007 INCREASE”;

20 (ii) striking “, in addition to adjust-
 21 ments under paragraphs (1) and (2), fur-
 22 ther”;

23 (iii) striking “established in sub-
 24 section (b)” and inserting “under sub-
 25 section (a)”;

(iv) striking “adjustment” each place it appears and inserting “increase”; and

(D) in paragraph (2), as so redesignated,

by—

(i) striking “establish, for the next fiscal year, and” and all that follows through “the fees” and inserting “publish in the Federal Register fees under subsection (a). The fees”;

(ii) striking “2003” and inserting “2006”; and

(iii) striking “\$154,000.” and inserting “\$259,600, and the fees established for fiscal year 2007 shall be based on a pre-market application fee of \$281,600.”;

(3) in subsection (d)(2)(A)—

(A) in clause (i), by striking “\$30,000,000” and inserting “\$75,000,000”;

and

(B) by striking clause (ii) and inserting the following:

“(ii) ADJUSTMENTS.—

“(I) IN GENERAL.—If the Secretary has evidence from actual experience that the \$75,000,000 threshold

1 established in clause (i) results in a
 2 reduction in revenues from premarket
 3 applications, premarket reports, and
 4 supplements that is 26 percent or
 5 more than would occur without small
 6 business exemptions and lower fee
 7 rates, the Secretary may—

8 “(aa) use the operating re-
 9 serves in an amount not to ex-
 10 ceed the lesser of—

11 “(AA) 10 percent of the
 12 fees collected in fiscal year
 13 2005; or

14 “(BB) \$2,500,000; and

15 “(bb) upon the exhaustion of
 16 the amount described under item
 17 (aa), adjust the \$75,000,000
 18 threshold as provided for under
 19 subclause (II).

20 “(II) ADJUSTMENT OF THRESH-
 21 OLD.—To adjust the threshold de-
 22 scribed in subclause (I)(bb), the Sec-
 23 retary shall publish a notice in the
 24 Federal Register setting out the ra-
 25 tionale for the adjustment, and the

1 new threshold. Such adjusted thresh-
 2 old may not be less than \$30,000,000
 3 and may not be retroactive.”;

4 (4) in subsection (e)(2)(A), by striking
 5 “\$30,000,000” and inserting “\$75,000,000”;

6 (5) in subsection (g)(1)—

7 (A) in subparagraph (B)—

8 (i) by striking clause (i) and inserting
 9 the following:

10 “(i) For fiscal year 2005, the Sec-
 11 retary is expected to meet all of the per-
 12 formance goals identified for the fiscal year
 13 if the amount so appropriated for such fis-
 14 cal year, excluding the amount of fees ap-
 15 propriated for such fiscal year, is equal to
 16 or greater than \$205,720,000 multiplied
 17 by the adjustment factor applicable to the
 18 fiscal year.”; and

19 (ii) in clause (ii), by striking the mat-
 20 ter preceding subclause (I) and inserting
 21 the following:

22 “(ii) For fiscal year 2005, if the
 23 amount so appropriated for such fiscal
 24 year, excluding the amount of fees appro-
 25 priated for such fiscal year, is more than

1 1 percent less than the amount that ap-
 2 plies under clause (i), the following ap-
 3 plies.”; and

4 (B) in subparagraph (C)—

5 (i) in the matter preceding clause (i),
 6 by—

7 (I) striking “2003 through” and
 8 inserting “2005 and”; and

9 (II) inserting “more than 1 per-
 10 cent” after “years, is”; and

11 (ii) in clause (ii), by striking “sum”
 12 and inserting “amount”;

13 (6) in subsection (h)(3)—

14 (A) in subparagraph (C), by striking the
 15 semicolon and inserting “; and”; and

16 (B) by striking subparagraphs (D) and (E)
 17 and inserting the following:

18 “(D) such sums as may be necessary for
 19 each of fiscal years 2006 and 2007.”; and

20 (7) by striking “subsection (e)(5)” each place it
 21 appears and inserting “subsection (e)(2)”.

22 (b) MISBRANDED DEVICES.—

23 (1) REPROCESSED DEVICES.—Section 502(u) of
 24 the Federal Food, Drug, and Cosmetic Act (21
 25 U.S.C. 352(u)) is amended to read as follows:

1 “(u)(1) Subject to paragraph (2), if it is a repro-
 2 essed single-use device, unless it, or an attachment there-
 3 to, prominently and conspicuously bears the name of the
 4 manufacturer of the reprocessed device, a generally recog-
 5 nized abbreviation of such name, or a unique and generally
 6 recognized symbol identifying such manufacturer.

7 “(2) The Secretary may by guidance waive any re-
 8 quirement under paragraph (1) for a reprocessed device
 9 or category of reprocessed devices if the Secretary deter-
 10 mines that compliance with such a requirement—

11 “(A) is not feasible due to the physical charac-
 12 teristics of the device or category of devices; or

13 “(B) would compromise the provision of reason-
 14 able assurance of the safety or effectiveness of the
 15 device or category of devices.”.

16 (2) GUIDANCE.—Not later than 150 days after
 17 the date of enactment of this Act, the Secretary of
 18 Health and Human Services shall issue guidance
 19 specifying the device or category of devices that
 20 qualify for a waiver under section 502(u) of the Fed-
 21 eral Food, Drug, and Cosmetic Act (21 U.S.C.
 22 352(u)) (as amended by paragraph (1)).

23 (3) EFFECTIVE DATE.—Section 301(b) of Pub-
 24 lic Law 107–250 (116 Stat. 1616), as amended by

1 section 2(c) of Public Law 108–214 (118 Stat. 575),
 2 is amended by—

3 (A) striking “36 months after the date of
 4 enactment of this Act” and inserting “9 months
 5 after the date of enactment of the Medical De-
 6 vice User Fee Stabilization Act of 2005”; and

7 (B) inserting “reprocessed and” before
 8 “introduced”.

9 **SECTION 1. SHORT TITLE.**

10 *This Act may be cited as the “Medical Device User*
 11 *Fee Stabilization Act of 2005”.*

12 **SEC. 2. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND**
 13 **COSMETIC ACT.**

14 (a) *DEVICE USER FEES.*—Section 738 of the Federal
 15 *Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amend-*
 16 *ed—*

17 (1) *in subsection (b)—*

18 (A) *after “2004;”, by inserting “and”; and*

19 (B) *by striking “2005;” and all that follows*
 20 *through “2007” and inserting “2005”;*

21 (2) *in subsection (c)—*

22 (A) *by striking the heading and inserting*
 23 *“ANNUAL FEE SETTING.—”;*

24 (B) *by striking paragraphs (1), (2), (3),*
 25 *and (4);*

(C) by redesignating paragraphs (5) and (6) as paragraphs (1) and (2), respectively;

(D) in paragraph (1), as so redesignated, by—

(i) striking the heading and inserting “IN GENERAL.—”;

(ii) striking “establish, for the next fiscal year, and” and all that follows through “the fees” and inserting “publish in the Federal Register fees under subsection (a). The fees”;

(iii) striking “2003” and inserting “2006”; and

(iv) striking “\$154,000.” and inserting “\$259,600, and the fees established for fiscal year 2007 shall be based on a premarket application fee of \$281,600.”; and

(E) by adding at the end the following:

“(3) SUPPLEMENT.—

“(A) IN GENERAL.—For fiscal years 2006 and 2007, the Secretary may use unobligated carryover balances from fees collected in previous fiscal years to ensure that sufficient fee revenues are available in that fiscal year, so long as the Secretary maintains unobligated carryover bal-

ances of not less than 1 month of operating reserves for the first month of fiscal year 2008.

“(B) NOTICE TO CONGRESS.—Not later than 14 days before the Secretary anticipates the use of funds described in subparagraph (A), the Secretary shall provide notice to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives.”;

(3) in subsection (d)—

(A) in paragraph (1), by inserting after the first sentence the following: “For the purposes of this paragraph, the term ‘small business’ means an entity that reported \$30,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates, partners, and parent firms.”; and

(B) in paragraph (2)(A), by—

(i) striking “(i) IN GENERAL.—”;

(ii) striking “subsection,” and inserting “paragraph,”;

1 (iii) striking “\$30,000,000” and in-
2 serting “\$100,000,000”; and

3 (iv) striking clause (ii);

4 (4) in subsection (e)(2)(A), by striking
5 “\$30,000,000” and inserting “\$100,000,000”;

6 (5) in subsection (g)(1)—

7 (A) in subparagraph (B)—

8 (i) by striking clause (i) and inserting
9 the following:

10 “(i) For fiscal year 2005, the Secretary
11 is expected to meet all of the performance
12 goals identified for the fiscal year if the
13 amount so appropriated for such fiscal
14 year, excluding the amount of fees appro-
15 priated for such fiscal year, is equal to or
16 greater than \$205,720,000 multiplied by the
17 adjustment factor applicable to the fiscal
18 year.”; and

19 (ii) in clause (ii), by striking the mat-
20 ter preceding subclause (I) and inserting the
21 following:

22 “(ii) For fiscal year 2005, if the
23 amount so appropriated for such fiscal
24 year, excluding the amount of fees appro-
25 priated for such fiscal year, is more than 1

1 *percent less than the amount that applies*
 2 *under clause (i), the following applies:*”;

3 *(B) in subparagraph (C)—*

4 *(i) in the matter preceding clause (i),*
 5 *by—*

6 *(I) striking “2003 through” and*
 7 *inserting “2005 and”; and*

8 *(II) inserting “more than 1 per-*
 9 *cent” after “years, is”; and*

10 *(ii) in clause (ii), by striking “sum”*
 11 *and inserting “amount”; and*

12 *(C) in subparagraph (D)(i), by inserting*
 13 *“more than 1 percent” after “year, is”;*

14 *(6) in subsection (h)(3)—*

15 *(A) in subparagraph (C), by striking the*
 16 *semicolon and inserting “; and”; and*

17 *(B) by striking subparagraphs (D) and (E)*
 18 *and inserting the following:*

19 *“(D) such sums as may be necessary for*
 20 *each of fiscal years 2006 and 2007.”; and*

21 *(7) by striking “subsection (c)(5)” each place it*
 22 *appears and inserting “subsection (c)(1)”.*

23 ***(b) ANNUAL REPORTS.***—*Section 103 of the Medical*
 24 *Device User Fee and Modernization Act of 2002 (Public*
 25 *Law 107–250 (116 Stat. 1600)) is amended—*

1 (1) *by striking “Beginning with” and inserting*
 2 *“(a) IN GENERAL.—Beginning with”; and*

3 (2) *by adding at the end the following:*

4 “(b) *ADDITIONAL INFORMATION.—For fiscal years*
 5 *2006 and 2007, the report described under subsection (a)(2)*
 6 *shall include—*

7 “(1) *information on the number of different*
 8 *types of applications and notifications, and the total*
 9 *amount of fees paid for each such type of application*
 10 *or notification, from businesses with gross receipts or*
 11 *sales from \$0 to \$100,000,000, with such businesses*
 12 *categorized in \$10,000,000 intervals; and*

13 “(2) *a certification by the Secretary that the*
 14 *amounts appropriated for salaries and expenses of the*
 15 *Food and Drug Administration for such fiscal year*
 16 *and obligated by the Secretary for the performance of*
 17 *any function relating to devices that is not for the*
 18 *process for the review of device applications, as de-*
 19 *fin ed in paragraph (5) of section 737 of the Federal*
 20 *Food, Drug, and Cosmetic Act (21 U.S.C. 379i), are*
 21 *not less than such amounts for fiscal year 2002 multi-*
 22 *plied by the adjustment factor, as defined in para-*
 23 *graph (7) of such section 737.”.*

24 (c) *MISBRANDED DEVICES.—*

1 (1) *IN GENERAL.*—Section 502(u) of the Federal
 2 *Food, Drug, and Cosmetic Act* (21 U.S.C. 352(u)) is
 3 amended to read as follows:

4 “(u)(1) Subject to paragraph (2), if it is a reprocessed
 5 single-use device, unless it, or an attachment thereto, promi-
 6 nently and conspicuously bears the name of the manufac-
 7 turer of the reprocessed device, a generally recognized abbrevi-
 8 vation of such name, or a unique and generally recognized
 9 symbol identifying such manufacturer.

10 “(2) If the original device or an attachment thereto
 11 does not prominently and conspicuously bear the name of
 12 the manufacturer of the original device, a generally recog-
 13 nized abbreviation of such name, or a unique and generally
 14 recognized symbol identifying such manufacturer, a repro-
 15 cessed device may satisfy the requirements of paragraph (1)
 16 through the use of a detachable label on the packaging that
 17 identifies the manufacturer and is intended to be affixed
 18 to the medical record of a patient.”.

19 (2) *GUIDANCE.*—Not later than 180 days after
 20 the date of enactment of this Act, the Secretary of
 21 Health and Human Services shall issue guidance to
 22 identify circumstances in which the name of the man-
 23 ufacturer of the original device, a generally recognized
 24 abbreviation of such name, or a unique and generally
 25 recognized symbol identifying such manufacturer, is

1 not “prominent and conspicuous”, as used in section
 2 502(u) of *Federal Food, Drug, and Cosmetic Act* (as
 3 amended by paragraph (1)).

4 (d) *EFFECTIVE DATE*.—Section 301(b) of the *Medical*
 5 *Device User Fee and Modernization Act of 2002* (Public
 6 Law 107–250 (116 Stat. 1616)), as amended by section 2(c)
 7 of Public Law 108–214 (118 Stat. 575), is amended to read
 8 as follows:

9 “(b) *EFFECTIVE DATE*.—Section 502(u) of the *Federal*
 10 *Food, Drug, and Cosmetic Act* (as amended by section 2(c)
 11 of the *Medical Device User Fee Stabilization Act of 2005*)—

12 “(1) shall be effective—

13 “(A) with respect to devices described under
 14 paragraph (1) of such section, 12 months after
 15 the date of enactment of the *Medical Device User*
 16 *Fee Stabilization Act of 2005*, or the date on
 17 which the original device first bears the name of
 18 the manufacturer of the original device, a gen-
 19 erally recognized abbreviation of such name, or
 20 a unique and generally recognized symbol identi-
 21 fying such manufacturer, whichever is later; and

22 “(B) with respect to devices described under
 23 paragraph (2) of such section 502(u), 12 months
 24 after such date of enactment; and

1 “(2) shall apply only to devices reprocessed and
2 introduced or delivered for introduction in interstate
3 commerce after such applicable effective date.”.

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109TH CONGRESS
1ST Session

S. 1420

[Report No. 109-107]

A BILL

To amend the Federal Food, Drug, and Cosmetic
Act with respect to medical device user fees.

JULY 25, 2005

Reported with an amendment